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Notice of Independent Review Decision

January 19, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Anterior lumbar interbody fusion at L3-L4 lateral approach, with removal of pedicle screw instrumentation at L4-5 and evaluation of fusion status at L4-5 with posterior lumbar decompression to include bilateral facetectomies posterolateral fusion and re-instrumentation at L3-4 with intra operative decision to perform re-instrumentation at L4-5 based on evaluation of fusion status with a two day length of stay.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This reviewer is a Board Certified Neurological Surgeon with over 17 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on xx/xx/xx.

04/01/2013: Initial Evaluation. **Subjective:** This male patient reports to PT after having a 360 fusion at L4-L5 vertebrae on January 18, 2013. The patient reports before that time, he has had severe numbness, tingling, and burning in both of his lower extremities as well as weakness. At this time, the patient reports 95% of his leg pain on the right side and the numbness on the right side has stopped. Left-sided pain in nature is a burning type of pain from lateral buttocks to the ankle. The intensity of the pain is 5/10. The duration of the pain is constant. The patient reports no aggravating symptoms. In the back, the nature of the pain is stabbing

and is a 5/10 at this time. This patient does report numbness in his left leg mainly in the lower leg in the top and bottom of the foot. Precautions at this time are no lifting greater than 10 pounds, no bending, no twisting for 3 months. Sleep at this time is very poor. The patient reports he is sleeping at most 1-2 hours per night. **Objective:** The patient enters PT with a soft brace for the lumbar spine as well as a slow unsteady gait. To come from sitting to standing and standing to sitting the patient is very unstable and slow. Palpation: The patient demonstrates sluggish reflexes, decreased sensation at L44-L5 dermatome on the left. MMT: Knee for flexion on the left is a 3/5 and the right 4/5, extension on the left is a 3/5 and the right is a 4/5, hip flexion on the left is a 4/5and the right is a 4/5, abduction and adduction on the left is a 3/5 and the right is a 4/5, ankle dorsiflexion on the left is a 4/5 and the right is a 5/5. Roomberg test at this time is 25 seconds with performance. Single leg balance on the left was 5 seconds with poor performance and the right was 20 seconds with fair performance. Optimal scores for this patient is 94 Difficulty and 88 for confidence. Back Index: 74% **Plan:** The patient to be seen 2-3 times a week for 2-3 weeks. PT to focus on decreasing pain, improving strength and stability, improving radicular symptoms, improving muscle spasm, improving ROM and flexibility, improving balance and proprioception, improving body mechanics, improving sensation, improving ADLs and function, and improving knowledge of HEP. This will be achieved aquatic therapy, by kinetic activities, therapeutic exercise, joint mobilization, soft tissue mobilization, neuromuscular reduction, ice/heat, and home exercise.

05/13/2013: X-Ray of the lumbar spine nine views. **Impression:** Stable appearance of the posterior fusion at L4-5. The pedicle screws posterior fixation plates, and intervertebral device are stable. There is no evidence for hardware failure. There is no instability on flexion and extension views or bending views.

09/24/2013: Myelogram Lumbar Spine. **Impression:** 1. Successful intrathecal contrast administration.

09/24/2013: Post Myelographic CT Lumbar Spine. **Impression:** 1. Status post L4-5 posterior spinal fusion, partial L4 laminectomy, and L4-5 interbody fusion cage. 2. Moderate central and anterior compression deformity of T12. 3. Multi-level disc bulges with vacuum disc at l1-2 and L3-4. 4. No central canal stenosis. 5. Multilevel neural foraminal narrowing 6. Upper lumbar scoliosis with left convexity and a scoliosis cobb’s angle of approximately 8 degrees.

01/16/2014: Individual Counseling Note. **Assessment:** This man is seen today in individual psychotherapy. He is completing the fourth day of his program and is making slow progress. He is not as hyper vigilant today and is not as pain focused. He is cooperative and admitted that he is beginning to understand a little bit more about the program. I redirected him several times. He is not as aloof or hyper vigilant today. He indicated that he is still having tremendous amount of pain and does not know if the program will work for him. He indicated that what he really needs is an epidural steroid injection but is willing to try the program and continue to see what will come of it.

01/21/2014: Follow Up Report. **Examination:** Patient is doing the same. He started pain management program last week. Pain is rated 8/10 on VAS. Current medications are Oxycodone 5mg and Soma. These medications are not helpful. **Assessment:** Poor pain control with current regimen. **Plan:** 1. Still needs injection, will submit for pre-authorization to WC 2. Decrease medications as tolerated. 3. Patient is to continue in the chronic pain program.

02/21/2014: Procedure Note. **Postoperative Diagnosis:** 1. Chronic low back pain. 2. Status post lumbar fusion 3. Lumbar radiculopathy. **Procedure:** 1. Caudal epidural steroid injection 2. Epidurogram

03/31/2014: Letter. **Exam:** Lumbar ROM was decreased in forward flexion secondary to pain. Plantar responses were flexor bilaterally. Gait was markedly antalgic. The patient had significant difficulty with heel and toe walk secondary to pain. Straight leg raise was positive on the left at 20 degrees and positive on the right at 75 degrees. **Impression:** 1. Recurrent lumbar radiculopathy 2. Recurrent herniated nucleus pulposus at L3-4 3. Adjacent level disease at L3-4 . 4. Lumbar mechanical/discogenic pain syndrome at L3-4. 5. Lumbago, status post anterior lumbar interbody fusion at L4-5 with posterior lumbar decompression, posteriolateral fusion and pedicle screw instrumentation at L4-5 for a previous history of lumbar spondylolisthesis at L4-5, grade I, with remote surgical decompression on the left at L4-5. **Recommendations:** Due to failure of conservative medical therapy including physical therapy and epidural steroid therapy, pain duration greater than six months, current neurologic status with evidence of the 3-4 mm retrolisthesis of L3 on L4 with associated vacuum disc phenomenon and herniated nucleus pulposus paracentrally and to the left with associated left greater than right sided foraminal stenosis and lateral recess stenosis, at this time I recommend: 1. Anterior lumbar interbody fusion at L3-4, lateral approach, with removal of pedicle screw instrumentation at L4-5 and evaluation of fusion status at L4-5 with posterior lumbar decompression, posteriolateral fusion and re-instrumentation at L3-4 with the intraoperative decision to perform re-instrumentation at L4-5 based on evaluation of fusion status.

04/22/2014: X-Ray Lumbar Spine-two views. **Impression:** 1. No instability on flexion and extension views. There is no lumbar vertebral fracture or spondylolisthesis. 2. Posterior fusion at L4-5 is stable. 3. Wedging of the anterior two-thirds of T12 of 20% to 30% is unchanged. 4. Spondylosis is unchanged.

05/07/2014: Pre-Surgical Psychological Evaluation. **Diagnosis:** 296.22 Major Depressive Disorder, moderate 300.00 Unspecified Anxiety Disorder, 300.82 Somatic Symptom Disorder, with predominant pain, persistent, moderate **Recommendations:** does not appear to present with any psychosocial stressors that would exclude him from undergoing this procedure at this time; hence, he is an appropriate candidate for the proposed spinal surgery consisting of Anterior lumbar interbody fusion at L3-4, lateral approach, with removal of pedicle screw instrumentation at L4-5 and evaluation of fusion status at L4-5 with posterior lumbar decompression, posteriolateral fusion and re-instrumentation at L3-4 with

the intraoperative decision to perform re-instrumentation at L4-5 based on evaluation of fusion status.

09/16/2014: UR. **Rationale for Denial:** Although the treating clinician, notes recurrent disc herniation with evidence of instability, this is not documented in the diagnostic imaging provided for review. The CT myelogram documented no disc herniation at L3-4, X-rays have not documented instability, as reported in the progress note. Additionally, the fusion at L4-L5 is not reported as a non-union suggesting the fusion mass to be intact at that level. Per discussion, the claimant underwent facetectomies at L4-L5 at the index procedure in January 2013 for a mild history of mild spondylosis. The claimant had a remote history of a left L4-L5 surgical decompression, date unknown. Without clinical instability of segmental instability of greater than 4.5mm, the guidelines would not support surgical intervention consisting of a lumbar spinal fusion. The request for inpatient two-day stay with anterior lumbar interbody fusion at L3-L4, lateral approach, with removal of pedicle screw instrumentation at L4-L5 and evaluation of fusion at L4-L5 with posterior lumbar decompression, to include bilateral facetectomies, posterolateral fusion, and re-instrumentation at L3-L4, with the intra-operative decision to perform re-instrumentation at L4-L5 based on evaluation of fusion status is not certified.

10/15/2014: MRI of the lumbar spine without and with contrast. **Impression:** 1. Interval post-operative changes at L4-5 disc space level, decompressive laminectomies, and _____. 2. Areas of foraminal narrowing which are at least moderate on the left at L5-S1, at least mild to moderate on the left at L4-5, and mild to moderate on the right at L3-4, as described level by level above, the full extent of which is sub optimally evaluated due to a degree of susceptibility artifact and the metallic instrumentation.

10/15/2014: X-Ray four views of the lumbar spine. **Impression:** Stable appearance of the lumbar spine

10/17/2014: Letter. **Exam:** Lumbar ROM was severe restricted in forward flexion secondary to pain. Tandem walk was severely restricted secondary to pain and balance. Straight leg raise was positive at 20 degrees on the left and 30 degrees on the right. **Impression:** 1. Recurrent lumbar radiculopathy 2. Recurrent herniated nucleus pulpous at L3-4 3. Adjacent level disease at L3-4 . 4. Adjacent level disease L3-4. 5. Lumbago, status post anterior lumbar interbody fusion at L4-5 with posterior lumbar decompression, posteriolateral fusion and pedicle screw instrumentation at L4-5 for a previous history of lumbar spondylolisthesis at L4-5, grade I, with remote surgical decompression on the left at L4-5. **Recommendations:** Due to failure of conservative medical therapy including physical therapy and epidural steroid therapy, pain duration greater than six months, current neurologic status with evidence of the 3-4 mm retrolisthesis of L3 on L4 with associated vacuum disc phenomenon and herniated nucleus pulposus paracentrally and to the left with associated left greater than right sided foraminal stenosis and lateral recess stenosis, at this time I recommend: 1. Anterior lumbar interbody fusion at L3-4, lateral approach, with removal of pedicle screw

instrumentation at L4-5 and evaluation of fusion status with posterior lumbar decompression to include bilateral facetectomies to thoroughly decompressive the nerve roots which may predispose the patient to iatrogenic instability, posterolateral fusion and pedicle screw re-instrumentation at L3-4 with the intraoperative decision to perform re-instrumentation at L4-5 based on the evaluation of the fusion status.

12/05/2014: UR. **Rationale for Denial:** This is a non-certification of an appeal of an anterior lumbar interbody fusion at L3-L4, lateral approach, with removal of pedicle screw instrumentation at L4-L5 and evaluation of fusion at L4-L5 with posterior lumbar decompression, to include bilateral facetectomies, posterolateral fusion, and re-instrumentation at L3-L4, with the intra-operative decision to perform re-instrumentation at L4-L5 based on evaluation of fusion status with a two day length of stay. The previous non-certification on November 06, 2014, was due to a lack of documentation of instability. The previous non-certification is supported. Additional records were not provided for review. The guidelines would not support fusion in the absence of objective documentation of instability. X-Rays noting significant instability of 4.5mm or greater were not provided. A psychosocial screening was not documented as is recommended. The claimant has had a prior surgery at L4-L5 without relief of symptoms or substantial changes in the physical examination findings correlating with the MRI to support an additional decompression. The request for an appeal of an anterior lumbar interbody fusion at L3-L4, lateral approach, with removal of pedicle screw instrumentation at L4-L5 and evaluation of fusion at L4-L5 with posterior lumbar decompression, to include bilateral facetectomies, posterolateral fusion, and re-instrumentation at L3-L4, with the intra-operative decision to perform re-instrumentation at L4-L5 based on evaluation of fusion status with a two day length of stay is not certified.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The previous adverse determinations are upheld. This patient has back injury dating back to Feb 24, 2012 causing back pain radiating into his right leg. He had a prior history of lumbar surgery at unspecified time prior to his injury. A Lumbar MRI on 3/25/12 showed multiple disc bulges with extruded fragment at L4/5 in left lateral recess on report as well as old T12 compression fracture. He also had EMG/NCV of lower extremities on 7/15/12 that showed severe right L4 and L5 radiculopathy. He had L4/5 anterior and posterior fusion with pedicle screw fixation on 1/22/13 with some initial improvement in right leg symptoms but new left leg pain. The patient had Lumbar xrays in July 2013, April 2014, and October 2014 that did not show instability or spondylolisthesis at L3/4 and stable fusion at L4/5. He also had Lumbar CT myelogram in September 2013 that shows multilevel disc bulges in lumbar area with neuroforaminal stenosis at multiple levels by report. His Lumbar MRI from Oct 2014 was compromised by hardware artifact. The patient fails to meet ODG criteria for lumbar fusion at L3/4 where there is no spondylolisthesis or 4.5 mm anterolithesis and there is no rationale for revisiting the L4/5 hardware as there is no breakage or loosening. For these reasons, Anterior lumbar interbody fusion at L3-L4 lateral approach, with removal

of pedicle screw instrumentation at L4-5 and evaluation of fusion status at L4-5 with posterior lumbar decompression to include bilateral facetectomies posterolateral fusion and re-instrumentation at L3-4 with intra operative decision to perform re-instrumentation at L4-5 based on evaluation of fusion status with a two day length of stay is not medically necessary at this time and should be denied.

Per ODG:
Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion," after 6 months of conservative care. For workers' comp populations, see also the heading, "Lumbar fusion in workers' comp patients." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of compliance with recommended conservative therapy. [For spinal instability criteria, see AMA Guides (Andersson, 2000)] For complete references, see separate document with all studies focusing on Fusion (spinal). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. Studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. (Gibson-*Cochrane*, 2000) (Savolainen, 1998) (Wetzel, 2001) (Molinari, 2001) (Bigos, 1999) (Washington, 1995) (DeBarard-*Spine*, 2001) (Fritzell-*Spine*, 2001) (Fritzell-*Spine*, 2002) (Deyo-*NEJM*, 2004) (Gibson-*Cochrane/Spine*, 2005) (Soegaard, 2005) (Glassman, 2006) (Atlas, 2006) According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the "carefully selected patient." (Resnick, 2005) (Fritzell, 2004) A recently published well respected international guideline, the "European Guidelines," concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments – including multidisciplinary approaches with combined programs of cognitive intervention and exercises – have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. (Airaksinen, 2006) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. (Ivar Brox-*Spine*, 2003) (Keller-*Spine*, 2004) (Fairbank-*BMJ*, 2005) (Brox, 2006) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (Bagnall-*Cochrane*, 2004) (Siebenga, 2006) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. (Wickizer, 2004) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. (Weiner-*Spine*, 2004) (Shah-*Spine*, 2005) (Abelson, 2006) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor

professional consensus on the appropriate indications for performing spinal fusion. (Deyo-*Spine*, 2005) (Weinstein, 2006) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout-Juratli, 2006) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (Martin, 2007) According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. (CMS, 2006) When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. (Burnett, 2006) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. (Hallett, 2007) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. (Derby, 2005) (Derby2, 2005) (Derby, 1999) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. (Martin, 2008) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. (Chou, 2008) This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. (Hansson, 2008) Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) In a study of 2,378 Washington State workers' compensation claimants who underwent fusion to assess the frequency, timing, and causes of death, the 3-year cumulative mortality rate post-fusion was 1.93% and analgesic-related deaths were responsible for 21% of all deaths and 31.4% of all potential life lost. (Juratli, 2009) A study to compare the surgical experience, clinical outcomes, and effect on body weight between obese and morbidly obese patients undergoing lumbar spine fusion surgery concluded that clinical outcomes were independent of the BMI of the patient, but the incidence of postoperative complications was significant in 45% of morbidly obese and 44%

of obese patients. The authors proposed that morbidly obese patients should undergo bariatric surgery before spine surgery in nonemergent situations. (Vaidya, 2009) For nonradicular low back pain with common degenerative changes, there is fair evidence that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function, and less than half of patients experience optimal outcomes (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics) following fusion. (Chou, 2009) Posterolateral bone-grafting fusion is not necessary when a Denis type-B thoracolumbar burst fracture associated with a load-sharing score of <or=6 is treated with short-segment pedicle screw fixation. (Dai, 2009) Discography (and not merely the fusion) may actually be the cause of adjacent segment disc degeneration. This study suggested that the phenomenon of accelerated adjacent segment degeneration adjacent to fusion levels may be, in part, explained by previous disc puncture if discography was used in segments adjacent to the fusion. (Carragee, 2009) Among Medicare recipients, the frequency of complex fusion procedures for spinal stenosis increased 15-fold in just 6 years. The introduction and marketing of new surgical devices and financial incentives may stimulate more invasive surgery. (Deyo-*JAMA*, 2010) Results of this study suggest that postmenopausal female patients who underwent lumbar spinal instrumentation fusion were susceptible to subsequent vertebral fractures within 2 years after surgery (in 24% of patients). (Toyone, 2010) A four-year follow-up of an RCT of instrumented transpedicular fusion versus cognitive intervention and exercises for disc degeneration with chronic low back pain concluded that this invasive and high-cost procedure does not afford better outcomes compared with the conservative treatment approach to low back pain, and this study should give doctors pause when recommending lumbar fusion surgery without compelling indications, particularly when strong back rehabilitation programs are available. (Brox, 2010) The ECRI health technology assessment concluded that the evidence is insufficient to support lumbar fusion being more effective (to a clinically meaningful degree) than nonsurgical treatments (intensive exercise and rehabilitation plus cognitive behavioral therapy) in patients with and without prior surgery. (ECRI, 2007) There is a high rate of complications (56.4%) in spinal fusion procedures, especially related to instrumentation. (Campbell, 2011) The draft AHRQ Comparative Effectiveness Research concluded that limited data suggests that fusion leads to greater improvement in back pain relief and function than physical therapy at 2-year followup, but whether the difference is clinically significant is unclear, and serious adverse events occurred in the fusion group but not the noninvasive-intervention group. (Clancy, 2012) Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

Lumbar fusion in workers' comp patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains "under study." It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. (Fritzell-*Spine*, 2001) (Harris-*JAMA*, 2005) (Maghout-Juratli, 2006) (Atlas, 2006) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 2006) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers' compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient

outcomes. Other predictors of poor results were number of prior low back operations, low household income, and older age. (DeBerard-*Spine*, 2001) (DeBerard, 2003) (Deyo, 2005) (LaCaille, 2005) (Trief-*Spine*, 2006) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. (LaCaille, 2007) A recent study of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. (Nguyen, 2007) A recent case-control study of lumbar fusion outcomes in worker's compensation (WC) patients concluded that only 9% of patients receiving WC achieved substantial clinical benefit compared to 33% of those not receiving WC. (Carreon, 2009) This large historical cohort study suggests that lumbar fusion may not be an effective operation in workers' compensation patients with disc degeneration, disc herniation, and/or radiculopathy, and it is associated with significant increase in disability, opiate use, prolonged work loss, and poor RTW status. (Nguyen, 2011) After controlling for covariates known to affect lumbar fusion outcomes, patients on workers' comp have significantly less improvement. (Carreon, 2010) The presidents of AAOS, NASS, AANS, CNS, and SAS issued a joint statement to BlueCross BlueShield recommending patient selection criteria for lumbar fusion in degenerative disc disease. The criteria included at least one year of physical and cognitive therapy, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological comorbidities (e.g. depression, somatization disorder), and absence of litigation or compensation issues. The criteria of denying fusion if there are compensation issues may apply to workers' compensation patients. (Rutka, 2011) On the other hand, a separate policy statement from the International Society for the Advancement of Spine Surgery disagrees that worker's compensation should be a contraindication for lumbar fusion. (ISASS, 2011) This study demonstrated a significant difference in outcomes after lumbar spinal fusion between workers' comp populations and those on long-term disability insurance. Both populations only achieved marginal improvement, but workers' comp had a clear, negative influence on outcome even when compared to disability patients. (Gum, 2012)

Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. (Eckman, 2005) This study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. (Carragee, 2006) Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. (Fernandez-Fairen, 2007) Patients with degenerative spondylolisthesis and spinal stenosis who undergo standard decompressive laminectomy (with or without fusion) showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically, according to the recent results from the Spine Patient Outcomes Research Trial (SPORT). (Weinstein-spondylolisthesis, 2007) (Deyo-NEJM, 2007) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. (Martin, 2007) A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration, concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. (Mirza, 2007) A comparison of surgical and nonoperative outcomes between degenerative spondylolisthesis and spinal stenosis patients from the SPORT trial found that fusion was most appropriate for spondylolisthesis, with or without listhesis, and decompressive laminectomy alone most

appropriate for spinal stenosis. (Pearson, 2010) The latest SPORT study concluded that leg pain is associated with better surgical fusion outcomes in spondylolisthesis than low back pain. (Pearson, 2011) Comparative effectiveness evidence from SPORT shows good value for laminectomy and/or bilateral single-level fusion after an imaging-confirmed diagnosis of degenerative spondylolisthesis [as recommended in ODG], compared with nonoperative care over 4 years. (Tosteson, 2011

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. (Lonner, 2007)

See also Fusion for adult idiopathic scoliosis.

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 20 degrees. (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. Spinal instability criteria includes lumbar inter-segmental movement of more than 4.5 mm. (Andersson, 2000) (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology correlated with symptoms and exam findings; & (4) Spine pathology limited to two levels; & (5) Psychosocial screen with confounding issues addressed. (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. (Colorado, 2001) (BlueCross BlueShield, 2002)

For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

ODG hospital length of stay (LOS) guidelines:

Discectomy (*icd 80.51 - Excision of intervertebral disc*)

Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) $26,219
Best practice target (no complications) -- *Outpatient*
Laminectomy (*icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root*)
Actual data -- median 2 days; mean 3.5 days (±0.1); discharges 100,600; charges (mean) $34,978
Best practice target (no complications) -- *1 day*
Note: About 6% of discharges paid by workers' compensation.
Lumbar Fusion, posterior (*icd 81.08 - Lumbar and lumbosacral fusion, posterior technique*)
Actual data -- median 3 days; mean 3.9 days (±0.1); discharges 161,761; charges (mean) $86,900
Best practice target (no complications) -- *3 days*
Note: About 15% of discharges paid by workers' compensation.
Lumbar Fusion, anterior (*icd 81.06 - Lumbar and lumbosacral fusion, anterior technique*)
Actual data -- median 3 days; mean 4.2 days (±0.2); discharges 33,521; charges (mean) $110,156
Best practice target (no complications) -- *3 days*
Lumbar Fusion, lateral (*icd 81.07 - Lumbar fusion, lateral transverse process technique*)
Actual data -- median 3 days; mean 3.8 days (±0.2); discharges 15,125; charges (mean) $89,088
Best practice target (no complications) -- *3 days*
Thoracic Fusion, posterior (*81.05 - Dorsal and dorsolumbar fusion, posterior technique*)
Actual data -- median 6 days; mean 8.1 days (±0.2); discharges 20,239; charges (mean) $159,420
Best practice target (no complications) -- *5 days*
Artificial disc (*84.65 - Insertion of total spinal disc prosthesis, lumbosacral*)
Actual data -- median 3 days; mean 2.6 days (±0.1); discharges 1,653; charges (mean) $65,041
Best practice target (no complications) -- *Never recommended*
Note: About 30% of discharges paid by workers' compensation.
Artificial disc revision (*84.68 – Revision/replacement artificial spinal disc prosthesis, lumbar*)
Actual data -- median 3 days; mean 4.4 days (±0.8); discharges 169; charges (mean) $58,355
Best practice target (no complications) -- *Never recommended*
X-Stop (*84.80 - Insertion or replacement of interspinous process device*)
Actual data -- median 1 days; mean 1.8 days (±0.1); discharges 4,177; charges (mean) $47,339
Best practice target (no complications) -- *Never recommended*
Kyphoplasty (*81.66 - Percutaneous vertebral augmentation*)
Actual data -- median 4 days; mean 5.4 days (±0.2); discharges 23,458; charges (mean) $46,593
Best practice target (no complications) -- *3 days*
Vertebroplasty (*81.65 - Percutaneous vertebroplasty*)
Actual data -- median 5 days; mean 6.3 days (±0.2); discharges 13,694; charges (mean) $37,444
Best practice target (no complications) -- *3 days*
IDET (*80.54 - Other and unspecified repair of the anulus fibrosus*)
Actual data -- no overnight stays
Best practice target (no complications) -- *Never recommended*
PIRFT (*80.59 - Other destruction of intervertebral disc*)
Actual data -- median 3 days; mean 6.6 days (±1.8); discharges 196; charges (mean) $41,249
Best practice target (no complications) -- *Never recommended*
SCS (*03.93 Implantation or replacement of spinal neurostimulator leads*)
Actual data -- median 1 day; mean 2.3 days (±0.2); discharges 3,998; charges (mean) $68,730
Best practice target (no complications) -- *1 day*
Intrathecal Pump (*86.06 - Insertion of totally implantable infusion pump*)
Actual data -- median 3 days; mean 5.4 days (±0.4); discharges 6,995; charges (mean) $62,325
Best practice target (no complications) -- *3 days*
Fracture of vertebral column (*03.53 - Repair of vertebral fracture*)
Actual data -- median 9 days; mean 13.4 days (±0.6); discharges 3,458; charges (mean) $156,940
Best practice target (no complications) -- *9 days*

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**